UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

THIS DOCUMENT RELATES TO ALL CASES

HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT ON FRAUD AGAINST TORRENT

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PRELIMINARY STATEMENT

Torrent's sale of finished dose valsartan-containing drugs from August 3, 2018 through August 17, 2018 constituted knowing fraud. On August 3, Torrent's API supplier, ZHP, informed Torrent that the valsartan API it had purchased was contaminated with NDMA, a genotoxic impurity. (Torrent SOMF ¶ 15, 53). Despite this unequivocal information, Torrent continued to sell its product as FDA approved, compendial compliant, valsartan. (SOMF ¶ 43). Torrent failed to recall the contaminated pills, failed to disclose the contamination, and continued to fraudulently sell its contaminated valsartan finished dose until August 17, 2018 when the first of many recalls was initiated. (Torrent SOMF ¶ 21).

Additionally, during this time, Torrent received numerous questions from customers regarding the status of the recall and whether or not Torrent's medication was contaminated. Prior to August 3, Torrent informed customers their product did not contain a genotoxic impurity, even though Torrent had not tested its product to confirm this statement. (SOMF ¶ 41). However, on August 3, after ZHP confirmed that Torrent's valsartan was, in fact, contaminated with NDMA, Torrent maintained its position. (SOMF ¶ 43). Rather than notifying customers that NDMA was present in Torrent's valsartan and a recall was imminent, Torrent continued to assert that there was no recall issued and no genotoxic compound in the medication (SOMF ¶ 41, 43). Even on the day a recall was issued, Torrent maintained its

misrepresentations and continued to tell customers Torrent's valsartan was not recalled. (*Id.*)

Torrent's communications with customers were driven by fear of losing profits, with no regard for the rights of those paying for the contaminated valsartan. For example, in an email between ZHP and Torrent quality from July 5, 2018, the companies discussed minimizing lost profits as a result of the contamination, stating, "Hopefully with our joint efforts, we could minimize the impact to our products and markets." (*See* SOMF ¶ 62-63). Just days later, Torrent's Chief Operating Officer wrote an email on July 17, 2018, which stated, "All customers have been back-ordered and every single day counts, as our failure to supply penalties will start kicking in..." (*Id.*).

TORRENT IS LIABLE FOR FRAUD AS A MATTER OF LAW

The fraud subclass includes New Jersey, which is representative of the laws of the other states in the subclass. The five elements of common-law fraud are: (1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages. *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 610, 691 A.2d 350, 367 (1997), citing *Jewish Ctr. of Sussex County v. Whale*, 86 N.J. 619, 624-25, 432 A.2d

521 (1981). These elements are established as a matter of law, pursuant to Fed. R. Civ. P. 56, based on the undisputed material facts.

First, after Torrent learned NDMA was in the valsartan it sold, Torrent began working with the FDA to initiate a recall. (SOMF ¶ 43). In the meantime, customers continued to ask Torrent if they product they purchased was recalled. (*Id.*) Despite the fact Torrent was actively working to initiate a recall, Torrent continued to tell

¹ The law is consistent in the states in Fraud subclass group C, See: **AK**: Cornelison v. TIG Ins., 376 P.3d 1255, 1270 (Alaska 2016); AR: Muccio v. Hunt, 2016 Ark. 178, 4–5, 490 S.W.3d 310, 312–13 (2016); **CO:** Bristol Bay Prods., LLC v. Lampack, 2013 CO 60, ¶ 26, 312 P.3d 1155, 1160; **DC:** Saucier v. Countrywide Home Loans, 64 A.3d 428, 438–39 (D.C. 2013); FL: Townsend v. Morton, 36 So. 3d 865, 868 (Fla. Dist. Ct. App. 2010); **ID:** Budget Truck Sales, LLC v. Tilley, 163 Idaho 841, 847, 419 P.3d 1139, 1145 (2018); **IA**: Lumley v. Advanced Data-Comm, Inc., 773 N.W.2d 562 (Iowa Ct. App. 2009); LA: Albe v. City of New Orleans, 2014-0186 (La. App. 4 Cir. 9/17/14), 150 So. 3d 361, 368, n.8, writ denied, 2014-2166 (La. 12/8/14), 153 So. 3d 445; MA: Balles v. Babcock Power Inc., 476 Mass. 565, 573–74, 70 N.E.3d 905, 913 (2017) MN: U.S. Bank N.A. v. Cold Spring Granite Co., 802 N.W.2d 363, 373 (Minn. 2011); NJ: SL Indus., Inc. v. Am. Motorists Ins. Co., 128 N.J. 188, 208, 607 A.2d 1266, 1277 (1992); NY: Morrow v. MetLife Invs. Ins. Co., 177 A.D.3d 1288, 1289, 113 N.Y.S.3d 421, 423 (2019); NC: Rowan Ctv. Bd. of Educ. v. U.S. Gypsum Co., 332 N.C. 1, 17, 418 S.E.2d 648, 658–59 (1992); **ND:** Diemert v. Johnson, 299 N.W.2d 546, 548 (N.D. 1980) (no materiality component); **OH:** Siegel v. Ringer, 2017-Ohio-6969, ¶ 32, 94 N.E.3d 1178, 1185; **OK**: Key Fin., Inc. v. Koon, 2016 OK CIV APP 27, ¶ 13, 371 P.3d 1133, 1137–38; **PR:** Microsoft Corp. v. Computer Warehouse, 83 F. Supp. 2d 256, 262 (D.P.R. 2000) (no materiality requirement) RI: McNulty v. Chip, 116 A.3d 173, 182–83 (R.I. 2015) (no materiality requirement); **SD:** Stabler v. First State Bank of Roscoe, 2015 S.D. 44, ¶ 19, 865 N.W.2d 466, 477 (no materiality requirement); VT: Felis v. Downs Rachlin Martin PLLC, 2015 VT 129, ¶ 13, 200 Vt. 465, 472, 133 A.3d 836, 842 (2015); VA: Corish v. Northcutt, 87 Va. Cir. 20 (2014); WA: Adams v. King Ctv., 164 Wash. 2d 640, 662, 192 P.3d 891, 902 (2008); WY: Singer v. Lajaunie, 2014 WY 159, ¶ 26, 339 P.3d 277, 285 (Wyo. 2014) (no materiality requirement).

customers no recall has been issued on its valsartan. (*Id.*) Even as late as August 17, which was when Torrent's first recall was issued, Torrent continued to misrepresent to customers its valsartan was not recalled. (*Id.*) This was a material misrepresentation of a presently existing fact.

Additionally, during this time and all time preceding, Torrent continued to misrepresent that its valsartan product was the FDA approved formulation that complied with the compendial requirements. This was not true, as Torrent was aware its valsartan was contaminated with genotoxic probable human carcinogen, NDMA.

Second, Torrent knew the above statements were untrue. Certainly, as of August 3, Torrent had actual knowledge aware that its valsartan did not comply with FDA requirements. (SOMF¶ 15, 38-49, 57). It knew that its valsartan *did* contain the genotoxic impurity NDMA and that it therefore did not meet the regulatory or compendial standards for valsartan. (*Id*.)

It also knew that the information it was providing to customers regarding the status of the recall and contamination was also not true as it directly conflicts with the information provided to them by ZHP.

Third, there was clearly an intent to have others rely on the misrepresentation by definition. Without these representations the valsartan could not be legally sold. Further, if Torrent told customers that it is in the midst of initiating a recall on

valsartan product, customers would immediately stop buying the product and ask to switch to another manufacturer's valsartan. The only way to protect sales and profits was to continue to tell customers that Torrent's valsartan is not recalled and does not contain NDMA and/or NDEA, and this aligns with Torrent's conversations during this time. (SOMF ¶ 62-63).

Fourth, reasonable reliance is established as a matter of law. No TPP would have been able to purchase the contaminated valsartan if the truth had been told – since the contaminated valsartan could not and would not have been marketed, and no retailer would have sold it. (SOMF ¶ 49, 57).

Fifth, Plaintiffs were certainly damaged by purchasing adulterated, contaminated valsartan, as if it was the FDA approved formulation, compliant with the compendial requirements. If the truth had been told that could never have happened, since the contaminated valsartan could not have been sold. The only question to be answered at trial is the calculation of the compensatory damages, as well as whether and in what amount punitive damages should be awarded.

CONCLUSION

For the foregoing reasons, Plaintiffs request entry of an Order granting partial summary judgment, pursuant to Fed. R. Civ. P. 56, against Torrent for fraud, saving only the amount of the compensatory damages, as well as whether punitive damages

should be awarded, and the amount of punitive damages, as issues to be determined at trial.

Dated: December 22, 2023

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